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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,300	ZANG, JINGWU Z	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/4/05, 2/4/08, 4/24/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-42* is/are pending in the application.

4a) Of the above claim(s) *34-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 2/4/05 and Applicant's amendments and responses filed 2/4/08 and 4/24/08 are acknowledged and have been entered.

2. Applicant's election without traverse of Group III (claims 31-33), and species of SEQ ID NO: 1-6 in Applicant's responses filed 2/4/08 and 4/24/08, respectively, is acknowledged.

Claims 31-33 read on the elected species.

Accordingly, claims 34-42 (non-elected groups I and II) are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 31-33 are currently being examined.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP, 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

4. The disclosure is objected to because of the following informality: There is a large space between paragraphs [0021] and [0022].

Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendatory material not supported by the originally filed disclosure is as follows:

a. In claim 32, "wherein the T cells are reactive against only SEQ ID NOS: 1-6". Although there is support for a composition comprising T cells wherein the only T cells

in the said composition are reactive against SEQ ID NO: 1, 2, 3, 4, 5 and 6, there is no support for T cells that are reactive against only SEQ ID NOS: 1-6, as T cells specific for each said SEQ ID NO may cross-react with other analog epitope peptides.

b. In claim 33, "wherein the vaccine consists essentially of T cells that are reactive against SEQ ID NOS: 1-6".

7. Claims 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising autologous T cells inactivated by irradiation, said T cells are reactive against SEQ ID NO: 1-6, does not reasonably provide enablement for an autologous T cell *vaccine* comprising inactivated T cells reactive against SEQ ID NO: 1-6, *against only SEQ ID NO: 1-6*, or wherein the vaccine *consists essentially of* the said T cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not disclose how to make and/or use the instant invention, a *vaccine comprising or consisting essentially of inactivated T cells that are reactive against, or only reactive against, SEQ ID NO: 1-6.* The specification has not enabled the breadth of the claimed invention because the claims encompass a composition that is a vaccine to be used prophylactically, including a vaccine composition comprising the said T cells that are only reactive against SEQ ID NO: 1-6, but aren't reactive against analog peptides of the said SEQ ID NO, a vaccine composition consisting essentially of T cells that are reactive against SEQ ID NO: 1-6 with other undisclosed T cells or components. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed vaccine composition can be made and/or used, including for prophylaxis. The specification discloses no working examples with regards to the use of the instant invention for prevention of disease *in vivo*.

The specification discloses that irradiated T cells specific for SEQ ID NO: 1-6, when administered to MS patients, results in a decline in EDSS (expanded disability status scores) and a decline in frequency of myelin-reactive T cells (especially Examples 5 and 6).

The specification does not disclose the T cell composition used prophylactically as a vaccine.

Evidentiary reference the Merck Manual teaches that a vaccine is a suspension of whole or fractionated bacteria or viruses that have been rendered nonpathogenic and is given to induce an immune response and prevent subsequent disease.

Evidentiary reference Encyclopedia Brittanica Online defines vaccine as a suspension of weakened, killed, or fragmented microorganisms or toxins or of antibodies or lymphocytes that is administered primarily to prevent disease.

With regard to the limitation "consisting essentially of," by using the term consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

Evidentiary reference Minohara *et al* (Tissue Antigens, 2001, 57: 447-456) teach "It is important to determine both T-cell reactivity to myelin proteins and the restriction HLA molecules used for the disease-related antigen presentation in MS in order to clarify the mechanisms for HLA class II-associated susceptibility to MS" (especially paragraph spanning columns 1 and 2 on page 448).

Thus evidentiary reference Minohara *et al* establish that it is unpredictable what T cells, which populations, and which myelin proteins, and by extension the myelin peptides recognized by the T cells will not materially affect the basic and novel properties of the invention, and what the basic and novel properties are.

The specification discloses that autoreactive T cells are generated by stimulation of PBMCs with the peptides consisting of SEQ ID NO: 1-6 (Example 1).

As to the issue of CTL that only react against a specific peptide, evidentiary reference Tourdot *et al* (J. Immunol. 1997, 159: 2391-2398) teach that CTL can be generated against an analog peptide that efficiently recruit a CTL repertoire specific for the corresponding original peptide (especially abstract), indicating that CTL may cross-react.

There is insufficient guidance in the specification as to how to make and/or use instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 33 is indefinite in the recitation of "consists essentially of T cells that are reactive against SEQ ID NO: 1-6" because it is not clear what is meant, *i.e.,* what the metes and bounds of the claim are.

10. With regard to Applicant's letter filed 2/4/05 regarding the inventor's name, it is unclear if the difference in the spelling of the inventor's name in the present application versus in the priority documents is the result of a clerical error, *i.e.,* Jingwu Z. Zang in the instant application versus Jingwu Z. Zhang in the priority documents. Although 37 CFR 1.48(f) will act to automatically correct an earlier identification of inventorship in a nonprovisional application by the filing of an initial executed oath or declaration, 37 CFR 1.48(f) is not applicable for national stage applications filed under 35 U.S.C. 371 where the inventorship has been erroneously named in the international application. Accordingly, if the inventorship set forth in the oath or declaration filed in the national stage application differs from the inventorship specified in the international application, the requirements of 37 CFR 1.497(d) must be satisfied. See MPEP 1893.01(e). Applicant is reminded that if Applicant intends to change inventorship, such change is a petitionable matter.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Eileen B. O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 1, 2008

/G.R. Ewoldt/
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